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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,382

06/19/2006

Toshiharu Arishima

2006_0961A

3109

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7590

03/24/2009

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EXAMINER

BETTON, TIMOTHY E

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

03/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,382	Applicant(s) ARISHIMA ET AL.	
	Examiner TIMOTHY E. BETTON	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-12 is/are pending in the application.
- 4a) Of the above claim(s) 4-7 and 10-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' Remarks filed on 31 December 2008 have been acknowledged and duly made of record.

Response to Arguments

Claims 1-3, 8-9 and 14-15 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hadvary et al. (U.S. 4,598,089).

Claims 1-3, 8-9 and 14-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hadvary et al. in view of Softly et al. (*Compositions of Representative SALA TRIM Fat Preparations*, J. Agric. Food Chem. (1994) vol. 42, pp. 461-467).

Applicants respectfully traverse each of these rejections.

Rejection under 35 U.S.C. § 102 (Hadvary et al.)

Applicants aver Hadvary et al. for allegedly failing to disclose the exact and specific type of LUU type and UUL type triacylglycerols. Applicants disclose a specific type according to the instant Remarks but such limitations are nowhere disclosed in any of the presently amended claims. Hadvary et al. is sufficient for the scope and content of what it discloses. Hadvary et al. teach long unsaturated lipase inhibitors which reasonably anticipates the presently amended claims in lieu of the current withdrawal of claims 4-7 and 10-13.

For the reasons already made of record in view of the amendments to the current claims, the rejection under Hadvary is maintained.

Rejection under 35 U.S.C. § 103 (Hadvary et al. in view of Softly et al.)

Applicants' further aver Hadvary et al. in view of Softly et al. for allegedly failing to teach Hadvary et al as a lipase inhibitor but as a test meal

It is of no immaterial importance whether the fats of applicants invention suppress the absorption of coexisting fats because the limitations in the claims directed to this particular suggest and/or limitation have been withdrawn. Thus, the teachings and modifications of Softly et al are still relevant individually for what the reference discloses and in combination with the teachings of Hadvary et al. Applicants' have presented no evidence to the contrary to sufficiently support and/or suggest that Hadvary et al. does not teach lipase inhibitors in all their variant derivatives.

Hadvary et cites specifically cites:

All Streptomyces strains which produce the lipase inhibitor, lipstatin are suitable for the purpose of the present invention, especially Streptomyces toxytricini 85-13, NRRL 15443, and its subcultures, mutants and variants (col. 6, lines 16-20).

Thus, for the reasons already made of record, the rejections as disclosed above are maintained.

Status of the Claims

Claims 4-7 and 10-13 are withdrawn. Claims 1-3 and 14-19 are cancelled. Claims 8 and 9 are pending further prosecution on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

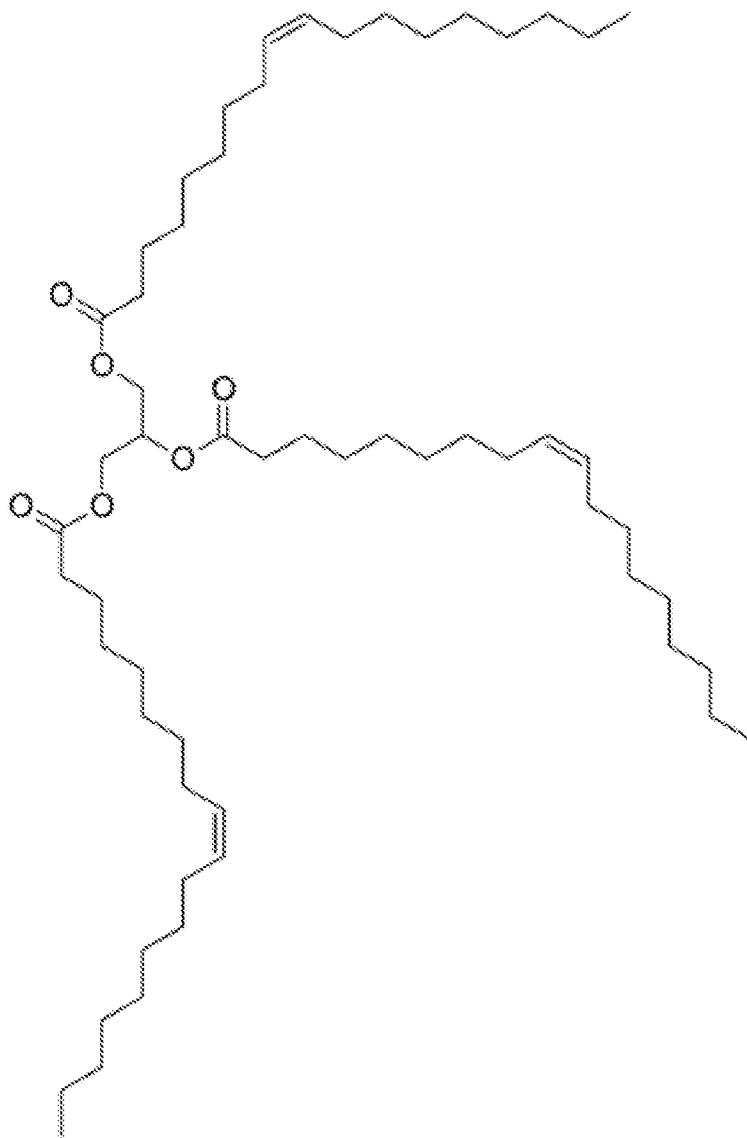
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Hadvary et al. (USPN 4,598,089).

Hadvary et al. teach long unsaturated lipase inhibitors (col 2, l/s 55-68).

Hadvary et al. teach the administration of a glyceryl ether lipid (i.e. H-triolein and C-oleic acid) as the active ingredient (col. 3, l/s 63).

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Hadvary et al. teach the content of these compounds incorporated in a test meal for animal subjects. The one of skill would instantly recognize that this same test meal could be optimized to the limitation disclosed in claim 6 draw' to a food product (col. 3, l/s 58-61).

As to the intended and function of the pharmaceutical composition recited in the claims, note, it is well settled that the "intended use" of a product or composition will not further limit claims drawn to a product or composition. See, e.g., *In re Hack* 114 USPQ 161. Further, an unrecognized property will not make an old product patentable. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Specifically, the unappreciated property of a prior art composition/compound and scientific explanation for the prior art's functioning is of specific import in view of the current invention. The disclosure that the triacylglyceryl component of a lipase inhibitor for instance can be readily manipulated and engineered in order to achieve a specific property and/or characteristic or size.

Hadvary et al. teach chemical structures rationally exemplifying the disclosure of claim 1 with regard to the particular characteristics of a LUU type triacylglyceryl. Obviousness is further supported and adequately suggested via the indicated therapeutic use of the compound as disclosed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hadvary et al. (USPN 4,598,089) in view of Softly et al. (Compositions of Representative SALATRIM Fat Preparations, J. Agric. Food Chem 1994, 42,461-467 (please see abstract, last line).

Hadvary et al. teach long unsaturated lipase inhibitors (col 2, l/s 55-68).

However, Softly et al. teach and disclose the random esterification of triacylglycerols containing a mixture of [...] long-chain fatty acids (please see abstract, last line).

Softly et al. teach a family of low-calorie fats called SALTRIM which are a mixture of triacylglycerols formed by the esterification of long-chain fatty acids.

Softly et al. teach the manipulation and engineering of the long-chain fatty acid ratio for specific products (Introduction, lines 22-28).

As to the intended and function of the pharmaceutical composition recited in the claims, note, it is well settled that the "intended use" of a product or composition will not further limit claims drawn to a product or composition. See, e.g., In re Hack 114 USPQ 161. Further, an unrecognized property will not make an old product patentable. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Specifically, the unappreciated property of a prior art composition/compound and scientific explanation for the prior art's functioning is of specific import in view of the current invention. The disclosure that the triacylglyceryl component of a lipase inhibitor for instance can be readily manipulated and engineered in order to achieve a specific property and/or characteristic or size.

Hadvary et al. teach chemical structures rationally exemplifying the disclosure of claim 1 with regard to the particular characteristics of a LUU type triacylglyceryl. Softly et al. supports and suggest the necessity of optimization in the pertinent art in order to determine optimal therapeutic effect. Obviousness is further supported and adequately suggested via the indicated therapeutic use of the compound as disclosed for both references incorporated.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shengjun Wang/

Primary Examiner, Art Unit 1617

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TEB